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P.O. Box 16446
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EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
4123	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,127	PESACH ET AL.	
	Examiner	Art Unit	
	CHU CHUAN LIU	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-2 and 4-17* is/are pending in the application.

4a) Of the above claim(s) *3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/06/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claim 3 is canceled by the applicant.

Drawings

2. The drawings are objected to because of the following informalities.

a. In regard to Fig. 1B, the element number "24" in the right of the figure should be corrected as "22".

b. In regard to Fig. 2A, Fig. 2A fails to show element "100" as described in the specification at line 2 on page 13.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: The word "bloody" should be read as "body" at line 6 on page 12 of the specification. The element number of glucometer "20" should be read as "80" at line 22 on page 13 of the specification. Appropriate correction is required.

Claim Objections

4. Claims 9, 10 and 13 are objected to because of the following informalities: In regard to claims 9, 10 and 13, the term "and" before "comprising" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 4, 6-8, 11-14 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,289,230 to Chaiken *et al.* (Chaiken). In regard to claim 1, Chaiken discloses Apparatus (apparatus, Col 22 lines 16-18) for assaying an analyte in blood in a blood vessel (blood glucose, Col 22 lines 5-41) below a patient's skin (fingertip, Col 22 lines 32-35) comprising: at least one light source controllable to transmit light into tissue below the skin (light source, Col 22 lines 16-38) through at least one first region on the skin (Col 22, lines 36-37); modulating apparatus that modulates the flow of blood through the blood vessel (Col 9 line 54- Col 10 line 3 or Col 22 lines 22-36); at least one light detector (CCD array, Col 22 lines 16-28) that receives a portion of the transmitted light that reaches at least one second region on the skin after propagating through the blood vessel (CCD array, Col 22 lines 16-42) and generates signals responsive to the received light and the modulation (Col 22 lines 33-53); and a controller (signal processor, Col 22 lines 16-32); wherein the controller controls the at least one light source (cavity diode laser, Col 22 lines 16-26) to transmit light at at least one wavelength that interacts with blood (785nm, Col 9 lines 10-37) and at at least one wavelength that interacts with the analyte (805nm or 808 nm for oxy- and deoxy-hemoglobin, Col 9 lines 10-37) and uses the signals responsive to the light that interacts

with the blood (Col 9 lines 26-37) to determine a location for the blood vessel (blood volume, Col 9 lines 26-39) and the determined location and signals responsive to the light to assay the analyte (concentration of analyte, Col 9 lines 26-37).

In regard to claim 2, Chaiken discloses the controller controls the at least one light source (cavity diode laser, Col 22 lines 16-26) and/or the at least one detector (CCD array, Col 22 lines 16-42) to transmit light between at least two pairs of first and second regions on the skin (fingertip, Col 22, lines 33-42) for which the distance between the first and second regions in one pair is different from that of the other pair (It is well known that the CCD array has multiple detecting elements. In either reflection or transmission geometry of the possible system configurations of Chaiken, the incident light and the reflected/ transmitted light would cover multiple pairs of first and second regions or each distance of one pair is different from that of other pair).

In regard to claim 4, Chaiken discloses the modulation apparatus comprises an ultrasound transmitter that illuminates the blood vessel with ultrasound (ultrasonic transducer, Col 9 line 54- Col 10 line 3).

In regard to claim 6, Chaiken discloses the modulation apparatus comprises a mechanical resonator that applies a time varying pressure to a region of the blood vessel (mechanical means, Col 11 lines 38-41).

In regard to claim 7, Chaiken discloses the controller determines the location responsive to the modulation of the signals (region of fingertip probed, Col 22 lines 16-53).

In regard to claim 8, Chaiken discloses the controller assays the analyte responsive to the modulation of the signals (blood-replete and blood-depleted stages, Col 9 lines 26-39).

In regard to claim 11, Chaiken discloses the at least one detector comprises a plurality of detectors (CCD array, Col 22 lines 16-28).

In regard to claim 12, Chaiken discloses the detectors comprise pixels in a CCD (CCD array, Col 22 lines 16-28).

In regard to claim 13, Chaiken discloses a lens that collects light from the at least one second region and focuses the light on the CCD (250mm f1.4 Nikon lenses, Col 22 lines 24-28).

In regard to claim 14, Chaiken discloses the light source comprises a single light source (cavity diode laser, Col 22 lines 16-26).

In regard to claim 16, Chaiken discloses the analyte is glucose (Col 8 lines 2-18).

In regard to claim 17, Chaiken discloses a method for assaying an analyte in blood in a blood vessel below a patient's skin (Col 8 lines 2-42) comprising: modulating the flow of blood through the blood vessel (Col 9 lines 26-38 and 55-66); transmitting light at at least one wavelength that interacts with blood (785nm, Col 9 lines 10-37), and is modulated responsive to the modulation (Col 9 lines 37-39) and at at least one wavelength that interacts with the analyte into tissue below the skin (805nm or 808 nm for oxy- and deoxy- hemoglobin, Col 9 lines 10-37), through at least one first region on the skin (Col 22 lines 33-39); generating signals responsive to a portion of the transmitted light at each of the at least one wavelengths (785nm, Col 22 lines 24-26)

that reaches at least one second region on the skin after propagating through the blood vessel (CCD array, Col 22 lines 16-42); using the signals responsive to the light that interacts with the blood to determine a location for the blood vessel (region of the fingertip probed, Col 16-53) and the determined location and signals responsive to the light to assay the analyte (Col 9 lines 26-39).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,289,230 to Chaiken *et al.* (Chaiken) as applied in claim 1, further in view of U.S. Patent No. 4,883,055 to Merrick (Merrick). In regard to claim 5, Chaiken discloses the modulation apparatus (tourniquet or ultrasonic transducer, Col 9 line 55 - Col 10 line 3). Chaiken does not specifically disclose the modulation apparatus comprises a source of electrical power that applies a time varying electric field to a region of the patient's body that causes recurrent tensing and relaxation of muscles that affect the size of the blood vessel. Merrick teaches the modulation apparatus (Fig. 5 of Merrick) comprises a source of electrical power (multifunctional patient monitor 30 and electrodes 36, Fig. 5 of Merrick) that applies a time varying electric field to a region of the patient's body that causes recurrent tensing and relaxation of muscles that affect the size of the blood

vessel (Col 2 lines 53-60). It is well known in the art at the time the invention was made that stimulating muscles by applying electrical field would cause contraction and further change the blood flow in a tissue. It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the modulation apparatus (Chaiken) as the electrode-based apparatus (Merrick) in order to have more precise modulation of the blood flow by stimulating muscles with an electrical field to cause contraction.

9. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,289,230 to Chaiken *et al.* (Chaiken) as applied in claim 1, further in view of U.S. Patent No. 5,360,004 to Purdy *et al.* (Purdy). In regard to claim 9, Chaiken discloses a light source (cavity diode laser, Col 22 lines 16-26) that transmit light to the at least one first region (fingertip, Col 22 lines 32-35). Chaiken does not specifically disclose a light pipe coupled to each of the at least one light source that transmit light from the light source to the at least one first region. Purdy teaches a light pipe (fiber optics conductor 29, Fig. 1) coupled to a light source (near infrared radiation source 13, Fig. 1) that transmit light from the light source to the at least one first region (portion 31 of mammal's body, Fig. 1). It is well known in the art that the energy loss in fiber optic conductors is very low. It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the light source (Chaiken) to incorporate a light pipe (Purdy) in order to have less energy loss during the transmission stage between the light source to the surface of desired region of skin.

In regard to claim 10, Chaiken discloses a light detector (CCD array, Col 22 lines 16-28) that receive light from the at least one second region. Chaiken does not specifically discloses a light pipe coupled to each of the at least one light detector that transmit light from the at least one second region to the detector. Purdy teaches a light pipe (fiber optic conductor 33, Fig. 1) coupled to the light detector (spectrum analyzer/ detector 21, Fig. 1) that transmit light from the at least one second region (portion 31 of mammal's body, Fig. 1) to the detector. It is known that the CCD array detector have many detecting elements and each element could receive a portion of light from adjacent elements. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the detector (Chaiken) to incorporate a light pipe(s) (Purdy) in order to reduce noise in the detected signal and have more accurate measurements.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,289,230 to Chaiken *et al.* (Chaiken) as applied in claim 1, further in view of U.S. Patent Application Publication No. 2002/0058865 to Cheng *et al.* (Cheng). In regard too claim 15, Chaiken discloses the light source (cavity diode laser, Col 22 lines 16-26) to illuminate a first region on the skin (fingertip, Col 22 lines 32-35). Chaiken does not specifically disclose the light source is controllable to be moved so as to illuminate different first regions on the skin. Cheng teaches a light source (movable member 120 and wave sources 122, Fig. 1) is controllable to be moved (guiding tracks 160, Fig. 1) so as to illuminate different first regions on the skin (Fig. 1). It would have

been obvious to one with ordinary skill in the art at the time of the invention was made to modify the light source (Chaiken) as the controllable light source (Cheng) in order to illuminate different regions of skin more efficiently without moving the entire apparatus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 8:00am~5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774